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Special 510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

SEP 22 2006

Date of Preparation: August 29th, 2006

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Germany

Device Information:

Trade Names: **Pajunks disposable Inserts for Handle Instruments and HF Electrodes**

Common Name: **Disposable Modular Inserts for Handle Instruments**

Classification Name: Disposable monopolar surgical instrument

Classification Reference: 21 CFR 876.1500, April 1. 2005

Poposed Classification: Regulatory Class: II

Proposed Product Code: GEI, GCJ

Predicate Devices: Pajunks monopolar electrodes marketed under **K033249**

P2.83

Device and Technology Description:

The Pajunk MIS-System contains but is not limited to electrode-inserts for comfortable and safe coagulation. PAJUNK has extended its range of instruments for MIS by a reuseable, modular system with disposeable inserts, which permits the economic replacement of the sensitive inserts.

The instrument inserts consist of four basic types: Grasping Forceps, Scissors, Biopsy Punches and Clamps /Needle Holders. All handles can be combined with all insulated shafts and instrument inserts, regardless of their size and shape.

The shaft screws onto the handle tightly, and it ensures the safe and secure connection of the two elements. Every module of the handle-instrument is kept in place in its bracing future, secured against distortion. A snap-on mechanism locks the instrument insert in the shaft: This whole element can then in turn be latched onto the handle by a special locking device. This latching of the connecting rod and the shaft minimizes the torsion stress exerted upon the instrument insert; the double security against distortion transfers the torque also to the entire shaft.

For the 1293- and 1292- Combination Handle an ergonomically placed switch allows the ratchet to be easily switched on or off during usage. Jacketed with glass fiber-reinforced plastic, the precise mechanical construction of the PAJUNK handle ensures maximum stability. Designed for left and right handed use, the ergonomically shaped handles are simple and comfortable to operate. The rotary wheel can be adjusted with a little pressure applied by the index finger. A built-in rotation stop secures the desired position when grasping.

And with that, PAJUNK® has created the option to always work and also to coagulate with new, guaranteed sharp scissors at every intervention. Three different sizes are available: micro, medium and large. They are packed individually, sterile, and they can be replaced very easily.

The fast and easy assembly is based on the ingenious locking mechanism. The scissor-insert is clicked into the connecting rod and tightly screwed together with the guidance tube. Please observe, that the replacement can only be carried out if the scissors are closed.Biocompatibility information for Pajunk's adaptable disposable inserts is located in Section 15.0 of this submission.

Intended Use

Pajunks disposable inserts are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Substantial Equivalence

Based on the information within this submission, it is our conclusion that Pajunk's reusable inserts marketed under 510(k) number **K033249**, and disposable inserts (subject device) are substantially equivalent.

Pajunk's electrodes are as safe and effective as the predicate devices when used by professional surgeons in accordance with the instructions for use supplied with these medical devices.

Conclusion:

The comparison between the predicate device and the proposed device demonstrates that the proposed Pajunk devices are at least as safe and effective as, as well as substantially equivalent to Pajunks predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2006

Pajunk GmbH Medizintechnologie
% Christian Quass
Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

Re: K062072
Trade/Device Name: Pajunks disposable inserts for Handle instruments and HF Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 29, 2006
Received: September 1, 2006

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number:

Device Name: **Pajunks disposable inserts for Handle Instruments and HF Electrodes**

Indications for Use:

Pajunks disposable inserts are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062072

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